



JUN 16 2000

3600 SW 47th Avenue  
 Gainesville, Florida 32608  
 TEL: 352/338-0440 FAX: 352/338-0662

**510(k) SUMMARY**

**APPLICANT:** Medical Device Technologies, Inc.  
 3600 SW 47<sup>th</sup> Avenue  
 Gainesville, FL 32608

**CONTACT:** Karl Swartz  
 Quality Assurance Manager

**TELEPHONE:** (352)338-0440  
 fax (352)338-0662

**TRADE NAMES:** PBN Hystero-Salpingography Catheter

**COMMON NAME:** Hystero-Salpingography catheter

**CLASSIFICATION NAME:** Cannula, Manipulator/Injector, Uterine

**SUBSTANTIAL EQUIVALENCE:**

<u>Company Name</u>	<u>Product Name</u>	<u>510(k) No.</u>
Ackrad Laboratories	H/S Catheter Set	K953034

**DESCRIPTION OF DEVICE:**

The PBN Hystero-Salpingography Catheter is comprised of a balloon bearing catheter, and a syringe to inflate the balloon.

The catheter material will be available in sizes ranging from 5 fr. to 7 fr., and is extruded from a flexible plastic tube, that is 30 to 40 cm in length. The distal end will have an end port. The balloon which is composed of a synthetic elastomer of a natural, clear kraton material is mounted 3 to 5 mm proximal to the distal end. The proximal end of the catheter is composed of a Y fitting leading to a stopcock for contrast media on one leg of the Y fitting, and a stopcock for inflating the balloon on the other leg of the Y fitting.

The syringe is a 5 cc size. The syringe has a vent at the 2.5 cc graduation providing that volume for inflation of the 5 fr. Balloon. The recommended volume for the 7 fr. Balloon is 3.0 cc.

**INDICATIONS FOR USE:**

The PBN Hystero-Salpingography Catheters are intended for use in the injection of contrast material in the examination of the uterus and fallopian tubes.





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 16 2000

Mr. Karl Swartz  
Quality Manager  
Medical Device Technologies, Inc.  
3600 SW 47th Avenue  
Gainesville, FL 32608

Re: K000433  
PBN Hystero-Salpingography Catheters  
Dated: April 28, 2000  
Received: May 1, 2000  
Unclassified  
Procode: 85 LKF

Dear Mr. Swartz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Daniel G. Schultz, M.D.  
Captain, USPHS  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure(s)



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510(k) Number (if known): K000433

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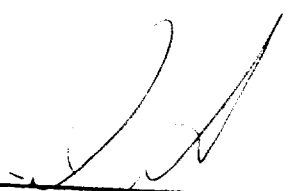
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
(Per 21 CFR 801.109)

OR Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K000433



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